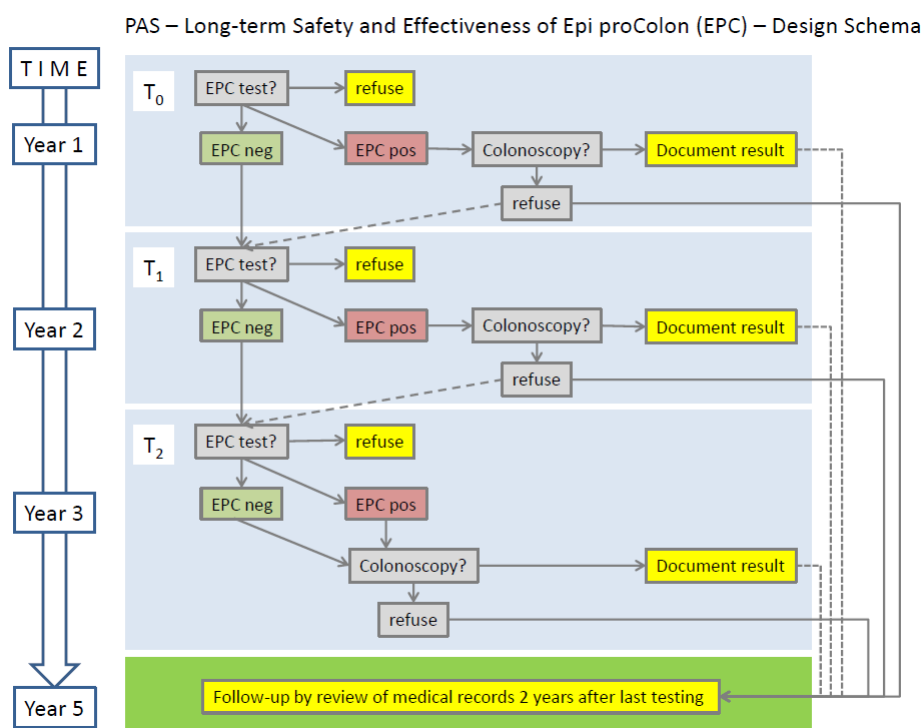


## Post Approval Study (PAS):

The post approval study proposal under consideration focused on determining the performance of the Epi proColon test when used over multiple years in a screening setting. The basic study scheme is outlined in Figure 1.

Figure 1: Flow diagram outlining the proposed PAS study on programmatic performance of the Epi proColon test.



### PAS Study Objective:

Determine the programmatic performance of Epi proColon (EPC) in a screening population of average risk for colorectal cancer (CRC) (consistent with proposed intended use population of the Epi proColon assay)

- Performance of EPC annual testing for 3 years evaluated according to the following:
  - Diagnostic yield: per round of testing & final
  - Test positivity, Positive Predictive Value (PPV): per round of testing & final
  - Programmatic sensitivity, Negative Predictive Value (NPV): final only
- Compliance to screening with EPC over time
- Adherence to diagnostic follow-up after positive EPC